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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,513	01/24/2002	Kurt C. Gish	05882.0175.NPUS01.	5387

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding. ...

<b>Office Action Summary</b>	<b>Application No.</b> 10/058,513	<b>Applicant(s)</b> GISH ET AL.	
	<b>Examiner</b> Stephen L. Rawlings, Ph.D.	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 40-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1 and 40-45 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. The election filed April 12, 2004 is acknowledged and has been entered.
2. The amendment filed April 12, 2004 is acknowledged and has been entered. Claims 1-6 and 8-39 have been canceled. Claims 40-45 have been added.
3. Claims 7 and 40-45 are pending in the application and in view of the amendment filed April 12, 2004 are currently subject to restriction.

#### *Election/Restrictions*

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 7 and 40-45, insofar as the claims are drawn to a method for diagnosing prostate cancer comprising determining the expression of a gene encoding the amino acid sequence set forth as SEQ ID NO: 2 or a fragment thereof, including the fragment of SEQ ID NO: 3, classified in class 435, subclass 6.

Group II. Claims 7 and 40-45, insofar as the claims are drawn to a method for diagnosing prostate cancer comprising determining the expression of a gene encoding a fragment of a protein, which fragment has the amino acid sequence set forth as SEQ ID NO: 4, classified in class 435, subclass 6.

Group III. Claims 7 and 40-45, insofar as the claims are drawn to a method for diagnosing prostate cancer comprising determining the expression of a gene encoding a fragment of a protein, which fragment has the amino acid sequence set forth as SEQ ID NO: 5, classified in class 435, subclass 6.

5. The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I-III are distinct methods, in that each method comprises a different step of measuring the expression of a gene encoding a distinct gene product, or a fragment thereof, having a distinct amino acid sequence. The Sequence Listing indicates that SEQ ID NO: 2 is the amino acid sequence of a protein designated "PBH1"; and it further indicates SEQ ID NO: 3 is a partial amino acid sequence of the protein PBH1. In addition, the Sequence Listing indicates that SEQ ID NO: 2 is the amino acid sequence of a protein designated "TRPC7", which is distinct from the protein designated PBH1; similarly, the Sequence Listing indicates that SEQ ID NO: 5 represents the amino acid sequence of a consensus between the amino acid sequences of the proteins designated PBH1 and TRPC7, which appears to be distinct from any fragment of either SEQ ID NO: 2 or SEQ ID NO: 4. Moreover, although claim 44 recites the fragments of SEQ ID NO: 4 and SEQ ID NO: 5 are fragments according to claim 7, which are fragments of PBH1, i.e., the protein of SEQ ID NO: 2, SEQ ID NO: 4 and SEQ ID NO: 5 do not actually appear to be fragments of PHB1, or the protein of SEQ ID NO: 2. Thus, if as claim 44 recites, SEQ ID NO: 4 and SEQ ID NO: 5 are in fact fragments of a protein designated "PBH1" in accordance with claim 7, then Applicant is designating three distinct gene products using the same nomenclature, namely "PBH1"; and since this fact was not recognized by the Examiner in preparing the previous restriction requirement set forth in the Office action mailed March 10, 2004, Applicant's amendment has necessitated this further restriction of the subject matter encompassed by claim 7. Accordingly, the inventions of groups I-III are distinct methods, in that each method comprises a different step of measuring the expression of a gene encoding a distinct gene product, or a fragment thereof, having a distinct amino acid sequence.

6. Because these inventions are distinct for the reasons given above and the search required for any one of groups I-III is not required for any other group, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler, Ph.D. can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1642

slr  
April 29, 2004

  
YVONNE EYLER, PH.D  
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